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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOON, SCARLETT Y

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4131

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,692	Applicant(s) EROMA ET AL.	
	Examiner SCARLETT GOON	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11 Feb 2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a National Stage entry of PCT/FI03/00533 filed on 2 July 2003 and claims priority to foreign application Finland 20021312 filed on 3 July 2002. A certified copy of the foreign priority document in Finnish is received.

Claim Objections

Claim 5 is objected to because of the following informalities: it is believed that the Applicants intended to use the word "being" in Claim 5 rather than as instantly written (beig). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The claims are vague and indefinite because the metes and bounds of the claims are not understood. It is unclear because claim 7 specifies "two or more polyols are non-segregating," indicating that the two or more polyols cannot be amorphous. However, claim 9, which is dependent on claim 7, specifies "said composition additionally contains a minor amorphous component of one or more of said polyols." The language of "two or more" in claim 7 requires a minimum of two polyols. Therefore, this would indicate that, in claim 9, the composition can only

Art Unit: 1625

contain one polyol as the minor amorphous component, rather than the indicated "one or more of said polyols."

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The claims are vague and indefinite because the metes and bounds of the claims are not understood. It is unclear because claim 11 specifies "said composition comprises an inner core portion which is different from the microcrystallized outer portion." However, claim 12, which is dependent on claim 11, specifies "said inner core preferably comprising milled maltitol, xylitol and/or lactitol in the same ratio as the ratio of maltitol, xylitol and/or lactitol in the microcrystalline outer core." The language of claim 11 requiring that the inner core be different from the outer core portion contradicts the specification of dependent claim 12 that requires the inner and outer core to have the same ratio of maltitol, xylitol and/or lactitol.

Claims 3, 4, 5, 12, 23, 24, 25, 26, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then

Art Unit: 1625

narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 3 recites the broad recitation of “a free moisture content below 1%,” and the claim also recites “preferably 0.05-0.5%” which is the narrower statement of the range/limitation.

In the present instance, claim 4 recites the broad recitation “from 25 to 75% by weight xylitol and from 75 to 25% by weight maltitol, ... from 25 to 75% by weight xylitol and from 75 to 25% by weight lactitol, or ... from 25 to 75% by weight lactitol and from 75 to 25% by weight maltitol.” The claim also recites “preferably 30% or more of both xylitol and maltitol, ... preferably 30% or more of both xylitol and lactitol, or ... preferably 30% or more of both lactitol and maltitol” as well as “preferably comprising equal amounts of said polyols” which is the narrower statement of the range/limitation.

In the present instance, claim 5 recites the broad recitation of “two of said polyols are present in at least 25% by weight each.” The claim also recites “preferably two of said polyols comprising 90% or more of the weight of said composition” as well as “most preferably all three of said polyols being present in 30% or more of the weight of said composition” which is the narrower statement of the range/limitation.

In the present instance, claim 12 recites the broad recitation that “said composition comprises an inner core of milled maltitol, xylitol and/or lactitol.” The claim also recites “said inner core preferably comprising milled maltitol, xylitol and/or lactitol in the same ratio as the ratio of maltitol, xylitol and/or lactitol in the microcrystalline outer core,” which is the narrower statement of the range/limitation.

In the present instance, claims 23 and 26 recite the broad recitation of “a particle size of less than 200 μm ,” and the claim also recites “preferably less than 100 μm ” which is the narrower statement of the range/limitation.

In the present instance, claim 24 recites the broad recitation of “the ratio of liquid feed to dry feed is between 2:1 and 1:4,” and the claim also recites “preferably between 1:1 and 1:2 on DS” which is the narrower statement of the range/limitation.

In the present instance, claim 30 recites the broad recitation for “a temperature of about 40-90°C ... to a free moisture content below 1%,” and the claim also recites “preferably about 65-72°C, most preferably about 67-70°C ... to a free moisture content ... preferably about 0.05 to 0.5%” which is the narrower statement of the ranges/limitations.

In the present instance, claim 31 recites the broad recitation for “a mean granule size of, on an average, 0.05 to 2 mm,” and the claim also recites “preferably 0.1 to 0.4 mm” which is the narrower statement of the range/limitation.

Claim 25 is rejected because it is dependent on claims 23 and 24 which are rejected because they do not clearly define the metes and bounds of the particle size of the dry feed, as well as the ratio of liquid feed to dry feed.

Claims 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 32-36 provide for the use of the microcrystallized polyol composition in confectionery, foodstuffs, oral hygiene products, pharmaceutical products and in dietetic products, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process Applicants are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-36 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 17-21 and 23 -37 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent 6,764,706 B1 to Heikkilä *et al.* and US Patent 5,017,400 to Olinger *et al.*, and further in view of published patent application WO 91/07100 to Oravainen *et al.*

The applied reference, US'400, has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not

Art Unit: 1625

claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Applicants claim a microcrystallized polyol composition, selected from the group consisting of maltitol, xylitol and lactitol, wherein said composition contains at least 25% by weight of each of at least two of said polyols. Applicants further claim a process for the microcrystallization of polyols into a polyol composition.

Heikkilä *et al.* (US 6,764,706) teaches a process for the crystallization of xylitol (claim 1), comprising the steps of (a) spraying an aqueous solution of xylitol, that is present at a concentration between 30% - 80% by weight, into contact with gas suspended fine solid particles containing microcrystalline xylitol, (b) causing substantial removal of the water solvent from said aqueous solution in the gas suspended state, and (c) causing said xylitol composition to be conditioned during a further drying step to provide a product consisting of microcrystals of xylitol agglomerated together in a random manner. The processed crystalline xylitol can be made into confectionery, foodstuffs,

Art Unit: 1625

pharmaceuticals, and oral hygiene products (section 1, lines 6 and 35 and claim 18).

To obtain a solid feed of said fine solid particles containing microcrystalline xylitol, Heikkilä *et al.* teaches that a portion of the microcrystalline xylitol particles, having a desired mean particle size below 0.2 mm (equivalent to 200 μm) are further recirculated (claim 17). In the absence of microcrystalline xylitol, the solid feed used at the start-up of the process may comprise milled crystalline xylitol from another source (column 2, line 62). Additionally, in example 3 of the reference, it is shown that powdered xylitol can also be used as the solid feed during start-up (column 8, line 57). Heikkilä *et al.* further indicates that the suitable ratio of liquid xylitol feed to solid xylitol feed varies with the microcrystallization conditions (column 5, line 25), and can therefore be adjusted accordingly.

For the process involving water solvent removal, Heikkilä *et al.* further stipulates that the process provide a xylitol material dried to a free moisture content of about 0.1% – 3% while said xylitol material is still in a suspended state (claim 6). Furthermore, the solid particles are to be retained in a fluidized state until they have grown to a predetermined weight (claim 16). The xylitol material is then collected by allowing it to settle on a moving belt and to form thereon a substantially continuous agglomerated porous powder layer (claim 8).

For the conditioning step in the process for crystallization of xylitol, Heikkilä *et al.* indicates that the microcrystallized particles are conditioned at a temperature of about 50 °C - 100 °C (claim 9). Thereafter, the microcrystalline xylitol particles are broken up so as to provide particles having a mean particle size of about 0.1 – 10 mm (claims 12 and 14), preferably about 0.15 – 0.4 mm (column 6, line 23). However, the reference teaches that xylitol particle size is not critical, and may be varied according to intended use of the product (column 3, line 12).

Heikkilä *et al.* also teaches that microcrystalline xylitol may be microcrystallized with other compounds (column 3, line 63). If the solid and/or liquid feed comprises other components, the product discharged from the microcrystallization apparatus will contain said other component(s) (column 3, line 65). These components can be an excipient, an active ingredient, and/or other sweetener (claim 3). An alternate process by which other components can be microcrystallized with xylitol is by using a secondary spray containing the excipient, active ingredient, or sweetener (column 4, line 1 and claim 4).

Heikkilä *et al.* does not teach the microcrystallization of a polyol composition comprising at least two polyols.

Olinger *et al.* (US Patent 5,017,400) teaches a sweetener composition which contains, as its principal ingredients, from about 10% - 90% by weight of crystalline maltitol and from about 90% - 10% by weight of crystalline xylitol. Xylitol is the sweetest

Art Unit: 1625

sugar-free alcohol and is considered isosweet to sucrose (column 1, line 38). Maltitol has a sweetness similar to that of sucrose, a sweetness equivalent to 0.8-0.9 of sucrose (column 2, line 8). Their comparable sweetness to sucrose makes these polyols ideal as sucrose replacements. The maltitol/xylitol sweetener composition is used to sweeten sugar-free products such as chocolate and other confectionery products, as well as dietetic products (column 1, line 9). Olinger *et al.* also teaches that this sweetener composition is noncariogenic and, in some instances, cariostatic (column 1, line 12).

Published patent application WO 91/07100 to Oravainen *et al.* teaches the sweetener of a hard candy that consists of 30% - 70% by weight of xylitol and 70% - 30% by weight of sorbitol, maltitol, isomalt, lactitol, or a mixture thereof. In example 2 of the published patent application, Oravainen *et al.* further teaches a sweetener composition comprising xylitol, sorbitol and maltitol.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heikkilä *et al.*, concerning the process for the crystallization of xylitol, with the teachings of Olinger *et al.*, which teaches a sweetener composition that contains a combination of maltitol and xylitol, with the teachings of Oravainen *et al.*, regarding the use of three polyols in a sweetener composition. One would have been motivated to combine the teachings in order to receive the expected benefit, as suggested by Olinger *et al.*, that a combination of xylitol and maltitol exhibits sweetness synergism, and also lacks the undesired burning taste of pure xylitol.

With regards to the art rejection above, it is noted that the Heikkilä *et al.* reference does not specifically teach a homogeneous and non-segregating composition of polyols as instantly claimed (claims 6, 7, 14 and 18). However, in the process for crystallization of xylitol, Heikkilä *et al.* does teach that an aqueous solution of xylitol be used. Therefore, since maltitol and lactitol are also water-soluble, it is expected that a solution containing a mixture of the polyols is uniform. Hence, when a mixture of the polyols is sprayed, it is expected that a homogeneous and non-segregating composition will result.

With regards to the art rejection above, it is also noted that the Heikkilä *et al.* reference does not specifically teach the simultaneous spraying of separate polyol solutions as instantly claimed (claim 21). However, Heikkilä *et al.* does teach that a secondary spray containing the excipient, active ingredient, or sweetener (column 4, line 1 and claim 4) may be used in the microcrystallization process. Therefore, it would be obvious to one skilled in the art that the individual solutions could be sprayed simultaneously.

Absent of any evidence to the contrary, and based upon the teachings of the prior art, there would have been reasonable expectation of success in utilizing the process described by Heikkilä *et al.* to crystallize a polyol composition comprising at least two polyols.

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,764,706 B1 to Heikkilä *et al.* and US Patent 5,017,400 to Olinger *et al.* as applied to claims 1-10, 17-21 and 23-37 above, and further in view of US Patent 5,580,601 to Ribadeau-Dumas *et al.*

Heikkilä *et al.* does not specifically teach the xylitol/maltitol ratio of 1:1 as instantly claimed (claim 13). Furthermore, the reference does not teach a eutectic mixture of xylitol and maltitol (instant claim 15), nor does it teach a specific enthalpy for a crystalline xylitol and crystalline maltitol composition (instant claim 16) as instantly claimed. This deficiency is addressed by Ribadeau-Dumas *et al.*

Ribadeau-Dumas *et al.* (US Patent 5,580,601) teaches a new grainy confectionery product obtained by the use of a suitable amount of maltitol or xylitol, as well as a process for manufacturing the said confectionery product. In example 5 (column 12, line 1), Ribadeau-Dumas *et al.* teaches a formulation of confectionery that comprises 4,360 g of xylitol (4,320 g + 40 g) and 4,370 g of maltitol. This quantity results in a 1:1 ratio of xylitol/maltitol.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heikkilä *et al.*, concerning the process for the crystallization of xylitol, with the teachings of Olinger *et al.*, which teaches a sweetener composition that contains a combination of maltitol and xylitol, with the teachings of Ribadeau-Dumas *et al.*, which teaches a grainy confectionery product that utilizes a

Art Unit: 1625

ratio of 1:1 xylitol/maltitol. One would have been motivated to combine the teachings in order to receive the expected benefit, as suggested by Olinger *et al.*, that a combination of xylitol and maltitol exhibits sweetness synergism, and also lacks the undesired burning taste of pure xylitol. Moreover, it would be considered that one of ordinary skill in the art would find it obvious to vary and/or optimize the ratios to provide the optimal conditions for crystallization of a polyol composition.

With respect to the melting point and enthalpy as instantly claimed (claims 15 and 16), these properties are specific and intrinsic to a compound and mixture. Additionally, as Applicants indicate (section 0071), an equimolar mixture of maltitol and xylitol (1:1 ratio) forms an eutectic mixture having a melting point different from that of the individual polyols, and also, the composition has a lower melting enthalpy than the calculated value for a combination of crystalline xylitol and crystalline maltitol. Therefore, the requirement for a eutectic mixture and a specified enthalpy would be attained when the optimal ratio of 1:1 has been achieved.

Regarding the recited homogenous and non-segregating composition of the polyols recited in Applicants' claims (claim 14), this limitation was addressed above in the §103 rejection of claims 1-10, 17-21 and 23-37, and the Office's position is herein incorporated by reference.

Absent of any evidence to the contrary, and based upon the teachings of the prior art, there would have been reasonable expectation of success in

utilizing the process described by Heikkilä *et al.* to crystallize a polyol composition comprising at least two polyols in varying ratios.

Claims 11, 12, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,764,706 B1 to Heikkilä *et al.* and US Patent 5,017,400 to Olinger *et al.* as applied to claims 1-10, 17-21 and 23-37 above, and further in view of US Patent 6,821,535 to Nurmi *et al.*

Heikkilä *et al.* does not teach a process for the microcrystallization of a polyol wherein said polyol is sprayed intermittently onto dry feed particles. Heikkilä *et al.* also does not teach a microcrystallized polyol composition that comprises an inner core portion that is different from the microcrystallized outer portion (claim 11) or that the ratio of maltitol, xylitol and/or lactitol in the inner and outer core be the same (claim 12). This deficiency is addressed by Nurmi *et al.*

Nurmi *et al.* (US Patent 6,821,535) teaches a process for the production of chewable coated cores by hard panning of chewable cores in a coating pan or drum. Syrup containing crystallizable polyol(s) and/or sugar(s) is intermittently sprayed over a rotating bed of the cores and the cores are dried between sprayings with a flow of air (Abstract and claim 1). Two kinds of syrup are generally used in the coating procedure (section 0057). The first syrup is typically used until an increase to a desired pellet weight is achieved, then the second syrup is used to build up the remainder of the coat (section 0058). Nurmi *et al.* teaches that the syrup coatings may contain other additives

Art Unit: 1625

such as flavors, pigments, special sweeteners and active ingredients (section 0059).

Furthermore, the coatings can be applied by spraying solutions containing other (besides and in addition to xylitol) dissolved and/or suspended polyols, especially sweeteners such as lactitol, maltitol, mannitol, isomalt and sorbitol (section 0061).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heikkilä *et al.*, concerning the process for the crystallization of xylitol, with the teachings of Olinger *et al.*, which teaches a sweetener composition that contains a combination of maltitol and xylitol, with the teachings of Nurmi *et al.*, which teaches a method of intermittent spray to coat chewable cores. One would have been motivated to combine the teachings in order to receive the expected benefit, as suggested by Nurmi *et al.*, for a quicker and more efficient coating process for polyols.

Absent of any evidence to the contrary, and based upon the teachings of the prior art, there would have been reasonable expectation of success in utilizing the step of intermittent spraying of polyols in the process described by Heikkilä *et al.* to crystallize a polyol composition comprising at least two polyols. Depending on the desired outcome, it would be obvious to one skilled in the art to select between spraying a solution that comprises a mixture, simultaneously spraying separate solutions of polyol, or intermittently spraying separate solutions of polyol.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,395,893 to Heikkilä *et al.* teaches a process for the crystallization of lactitol, as well as the use of the crystallized lactitol in a tablet, or in edible, pharmaceutical or oral hygiene products. US Patent 5,376,389 to Reed *et al.* teaches a dual composition hard coated chewing gum comprising xylitol and a non-xylitol polyol. US Patent 6,756,490 to Nurmi *et al.* teaches a method for the crystallization of maltitol.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang can be reached on 571-272-0562 or Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1625

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 4131

/Janet Andres/

Supervisory Patent Examiner, Art Unit 4131